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09/605,213	06/28/2000	Norbert Rahn	P00,1268	6581

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EXAMINER

MANTIS MERCADER, ELENI M

ART UNIT PAPER NUMBER

3737

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12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/605,213

Applicant(s)

RAHN ET AL.

Examiner

Eleni Mantis Mercader

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-10, 15-22 and 31-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-10, 15-22 and 31-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Objections

1. Claims 15, 3-10, 16-22 and 31-33 are objected to because of the following informalities: use of the terms "said examination subject" and "said first subject" in claims 15 and 16 is objected to in that they imply that the human subject is part of the apparatus. Please amend to further clarify, such as by substituting with terms: --the examination subject-- and --the first subject--. Appropriate correction is required.
2. Claim 7 is objected to because of the following informalities: in the newly provided clean copy "products" should be --produces--. Appropriate correction is required.
3. Claim 9 is objected to because of the following informalities: in the newly provided clean copy "an" should be --and--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 15, 3-10 and 31-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: a system component or means being set forth for determining the distance of the tip from the 2D image plane prior to mixing a designation of a distance of the tip from the image plane.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 15, 3-10 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paltieli'029 in view of Ferre et al.'980, both of record.

Paltieli'029 teaches all the features of the instant invention including: a system, a medical workstation, and a method comprising:

an image acquisition unit for acquiring image signals of a first subject an imaging unit for producing an image of the first subject from the image signals (see Figure 1, element 28, col. 6, lines 20-28);

a navigation system including a position acquisition system for determining a position of said image signal acquisition unit (see Figure 1, element 20; and col. 6, lines 29-40) and for

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determining a position of a second subject relative to said image acquisition unit (see Figure 1, element 32; and col. 6, lines 40-57);

a mixing unit for mixing a representation of said second subject into said image of said first subject (col. 7, lines 42-67 and col. 8, lines 1-63; also see Figures 7-10).

Paltieli'029 teaches a navigation system including identifiers, selected from the group consisting of detectable marks and position sensors, which are respectively attachable to said image signal acquisition unit and to said second subject and which are identifiable as to position by said position acquisition unit (see Figures 1 and 4; in Figure 4, elements 60 and 62; also see col. 6, lines 66-67 and col. 7, lines 1-18).

Paltieli'029 teaches the image signal acquisition unit which comprises an ultrasound probe (Figure 1, element 28; col. 6, lines 23-27).

Paltieli'029 teaches the image signal acquisition unit comprising an X-ray source and an X-ray receiver (see Figure 2, elements 42 and 40; and col. 6, lines 58-65).

Paltieli'029 teaches the imaging unit producing a 3D image of said first subject from said image signals (col. 8, lines 32-63).

Paltieli'029 teaches the imaging unit producing a 2D image of said first subject from said image signals (col. 8, lines 20-31) and wherein the mixing unit mixes an indication of a distance of the second subject from the image plane into the 2D image (see Figures 7-10; in Figure 8 see screen 106, indicating needle 92 on ultrasound image 108; also see col. 8, lines 11-32).

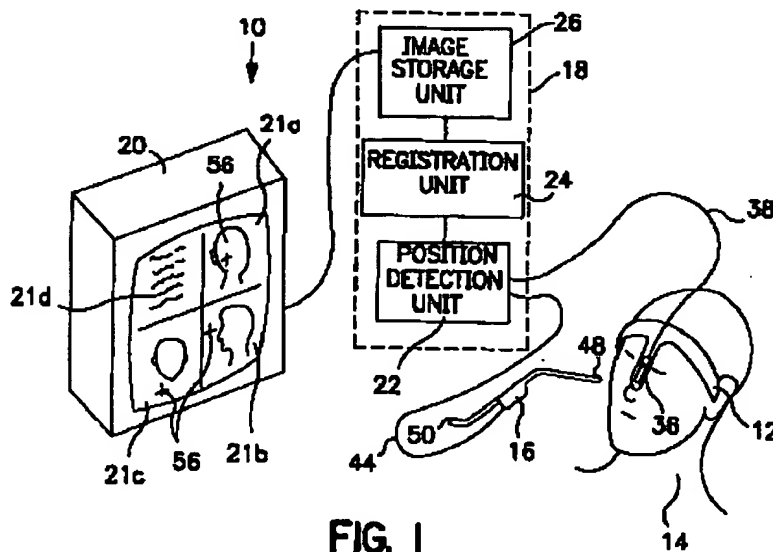
Paltieli'029 teaches the position acquisition unit simultaneously identifies the position of said image signal acquisition unit and the position of the second subject and indicating a

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projection of the tip into the 2D image as indicated by the dotted line (see Figures 4 and 7; and col. 6, lines 66-67 and col. 7, lines 1-67).

Paltieli'029 teaches an acceptance device for the first subject and wherein the position acquisition device identifies a position of the acceptance device simultaneously with identifying the position of the image signal acquisition unit and the position of the second subject (the verification computer unit constitutes such a device for verifying needle insertion based on positions of the subject based on the ultrasound image and the target; see col. 9, lines 46-63).

Paltieli'029 does not teach a mixing unit connected to the imaging unit for mixing a representation of said tip into said 2D image and if the said tip is not located in said image plane, for mixing a designation of the distance of the tip from the image plane into the 2D image said designation being alterable and indicating a magnitude of said distance.

**FIG. 1***Figure 1 of Ferre et*

al. '980 indicates the alterable position of the instrument with respect to its distance from the patient as displayed on the image, indicated in 21a, or outside of the image as indicated in 21b or 21c by element 56

In the same field of endeavor, Ferre et al.'980 teach in stereotactic systems utilization of a mixing unit for creating a composite image of the location of the tip as well as the tube of an

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instrument (see col. 5, lines 28-42). Ferre et al.'980 further teach mixing a representation of the tip in the 2D image as indicated in Figure 1, as displayed by "x" in coronal image 21a, wherein the position of the tip 56 is located into the 2D image. Ferre et al.'980 further teach that if the tip 56 is not located in the image plane but a distance away, mixing a designation of the distance of the tip from the image plane into the 2D image, notice in particular the sagittal image plane 21b and the axial image plane 21c of Figure 1, both indicating that the tip 56 is not located in the image plane but a distance away, and mixing a designation of the distance of the tip namely by using "x" indicated as element 56 which itself indicates the magnitude of distance from the 2D image. These positions are alterable by movement of the instrument as this is a localizing system tracking the position of the tip (col. 5, lines 28-42).

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Paltieli'029 and incorporated the teaching of Ferre et al.'980 to allow for better position monitoring of the instrument while in surgery in different imaging planes.

9. Claims 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paltieli'029 in view of Ferre et al.'980 as applied to claim 15 above, and further in view of Manwaring et al.'819.

Regarding claim 32, Paltieli'029 in view of Ferre et al.'980 teach all the features of the instant invention except for the teaching of using a circle having a diameter, which is alterable according to the magnitude of the distance. Manwaring et al.'819 teach using a circle having a diameter, which is alterable according to the magnitude of the distance (col. 10, lines 23-25; referring to distance-to-target feature circle 126 changing according to the distance of the probe tip from the target). It would have been obvious to one skilled in the art at the time that the

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invention was made to have modified Paltieli'029 in view of Ferre et al.'980 and incorporated the teaching of Manwaring et al.'819 to incorporate the distance-to-target feature circle 126 and superimpose this feature to all of the planes of interest, sagittal, coronal and axial to further assist the operator in determining how far the tip of the probe is from the target of interest as related to all of the planes of interest.

Regarding claim 33, Paltieli'029 in view of Ferre et al.'980 teach all the features of the instant invention except for the teaching of using color to guide the instrument. Manwaring et al.'819 teach using different colors in the 4 quadrants to further guide targeting the instrument (col. 8, lines 25-44). It would have been obvious to one skilled in the art at the time that the invention was made to have modified Paltieli'029 in view of Ferre et al.'980 and incorporated the teaching of Manwaring et al.'819 in order to easily determine the location of the instrument and its distance to target by using the different colors to further assist in localizing the instrument.

10. Claims 16-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paltieli'029 in view of Ferre et al.'980, both of record, and Cosman'072.

Paltieli'029 teaches all the features of the instant invention including: a system, a medical workstation, and a method comprising:

an image acquisition unit for acquiring image signals of a first subject an imaging unit for producing an image of the first subject from the image signals (see Figure 1, element 28, col. 6, lines 20-28);

a navigation system including a position acquisition system for determining a position of said image signal acquisition unit (see Figure 1, element 20; and col. 6, lines 29-40) and for

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determining a position of a second subject relative to said image acquisition unit (see Figure 1, element 32; and col. 6, lines 40-57);

a mixing unit for mixing a representation of said second subject into said image of said first subject (col. 7, lines 42-67 and col. 8, lines 1-63; also see Figures 7-10).

Paltieli'029 teaches a navigation system including identifiers, selected from the group consisting of detectable marks and position sensors, which are respectively attachable to said image signal acquisition unit and to said second subject and which are identifiable as to position by said position acquisition unit (see Figures 1 and 4; in Figure 4, elements 60 and 62; also see col. 6, lines 66-67 and col. 7, lines 1-18).

Paltieli'029 teaches the image signal acquisition unit which comprises an ultrasound probe (Figure 1, element 28; col. 6, lines 23-27).

Paltieli'029 teaches the image signal acquisition unit comprising an X-ray source and an X-ray receiver (see Figure 2, elements 42 and 40; and col. 6, lines 58-65).

Paltieli'029 teaches the imaging unit producing a 3D image of said first subject from said image signals (col. 8, lines 32-63).

Paltieli'029 teaches the imaging unit producing a 2D image of said first subject from said image signals (col. 8, lines 20-31) and wherein the mixing unit mixes an indication of a distance of the second subject from the image plane into the 2D image (see Figures 7-10; in Figure 8 see screen 106, indicating needle 92 on ultrasound image 108; also see col. 8, lines 11-32).

Paltieli'029 teaches the position acquisition unit simultaneously identifies the position of said image signal acquisition unit and the position of the second subject and indicating a

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projection of the tip into the 2D image as indicated by the dotted line (see Figures 4 and 7; and col. 6, lines 66-67 and col. 7, lines 1-67).

Paltieli'029 teaches an acceptance device for the first subject and wherein the position acquisition device identifies a position of the acceptance device simultaneously with identifying the position of the image signal acquisition unit and the position of the second subject (the verification computer unit constitutes such a device for verifying needle insertion based on positions of the subject based on the ultrasound image and the target; see col. 9, lines 46-63).

Paltieli'029 does not teach a mixing unit connected to the imaging unit for mixing a representation of said tip into said 2D image and if the said tip is not located in said image plane, for mixing a designation of the distance of the tip from the image plane into the 2D image said designation being alterable and indicating a magnitude of said distance.

In the same field of endeavor, Ferre et al.'980 teach in stereotactic systems utilization of a mixing unit for creating a composite image of the location of the tip as well as the tube of an instrument (see col. 5, lines 28-42).

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Paltieli'029 and incorporated the teaching of Ferre et al.'980 to allow for better position monitoring of the instrument while in surgery. Ferre et al.'980 further teach mixing a representation of the tip in the 2D image as indicated in Figure 1, as displayed by "x" in coronal image 21a, wherein the position of the tip 56 is located into the 2D image. Ferre et al.'980 further teach that if the tip 56 is not located in the image plane but a distance away, mixing a designation of the distance of the tip from the image plane into the 2D image, notice in particular the sagittal image plane 21b and the axial image plane 21c of Figure 1, both indicating

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that the tip 56 is not located in the image plane but a distance away, and mixing a designation of the distance of the tip namely by using "x" indicated as element 56 which itself indicates the magnitude of distance from the 2D image. These positions are alterable by movement of the instrument as this is a localizing system tracking the position of the tip (col. 5, lines 28-42).

Paltieli'029 in view of Ferre et al.'980 teach all the features of the instant invention except for a support mechanism and a mixing unit for mixing a representation of the treatment device into the image of the subject dependent on the position of the image acquisition unit, the support mechanism, and the treatment device relative to the signal acquisition unit. In the same field of endeavor, Cosman'072 teaches an optical tracking system to track and coordinate the treatment device (LINAC), the ultrasound imager, the patient and the couch/bed/or support as indicated in Figures 1 and 7 (see col. 8, lines 43-55 and col. 14, lines 20-42). It would have been obvious to one skilled in the art at the time that the invention was made to have modified Paltieli'029 in view of Ferre et al.'980 and incorporated the teaching of Cosman'072 to track all of the elements of the system relative to each other in order to more accurately guide treatment and adjust treatment when the patient moves (see for motivation to combine col. 2, lines 13-37, describing need for determining the positional relationships of the elements of the system to effectuate accurate treatment).

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Acker'439 teach a localizing system wherein if the tip of the instrument is not located in the image plane, then mixing a designation of a distance of the tip from the image plane into the

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2D image the designation being alterable and indicating the magnitude of the distance (see Figure 3 wherein a localizing system of a flexible catheter which continually monitors its location and orientation, allows the operator to visualize a “far plane”, FP, at a particular as indicated distance D_{FP} from the tip of the flexible catheter in order to allow the operator to guide the tip at the desired FP (also see col. 9, lines 30-67 and col. 10, lines 1-38) and wherein the distance is alterable at any direction of choice (see in particular col. 10, lines 60-67 and col. 11, lines 1-21)).

Schmitz et al.'724 teach using emitters on the patient's bed (see elements 10 of Figure 1).

Kuth et al.'663 teach an apparatus for treatment with acoustic waves having laser diodes 27a-27j aligned around the patient table in order to properly align the ultrasonic treatment (see Figure 1).

Yanof et al.'592 teach an integrated fluoroscopic projection image data, volumetric image data, and surgical device position data (note marker 16 located on patient support).

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eleni Mantis Mercader whose telephone number is 703 308-0899. The examiner can normally be reached on Mon. - Fri., 8:00 a.m.-6:30 p.m.. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef can be reached on 703 308-3256. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3590 for regular communications and 703 308-0758 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0858.



Eleni Mantis Mercader
Examiner
Art Unit 3737

EMM
April 1, 2003